

EXHIBIT 1

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FOR THE DISTRICT OF MASSACHUSETTS

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IN RE: PHARMACEUTICAL : MDL NO. 1456
INDUSTRY AVERAGE WHOLESale : CIVIL ACTION
PRICE LITIGATION : 01-CV-12257-PBS
THIS DOCUMENT RELATES TO :
U.S. ex rel. Ven-a-Care of : Judge Patti B. Saris
the Florida Keys, Inc. :
v. :
Abbott Laboratories, Inc., : Chief Magistrate
No. 06-CV-11337-PBS : Judge Marianne B.

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(CROSS NOTICED CAPTIONS ON FOLLOWING PAGES)
Videotaped deposition of DR. ROBERT BERENSON

Volume I

Washington, D.C.
Wednesday, December 18, 2007
10:10 a.m.

1 Academy Health, which is the organization that
2 represents health services researchers. I had a desk
3 there, but I was basically working as an independent
4 consultant doing health policy projects.

5 Q. Anything related to the reimbursement of
6 Medicare Part B drugs?

7 A. No.

8 Q. Anything related to Medicaid?

9 A. No.

10 Q. And then before that?

11 A. Before that, I worked at HCFA.

12 Q. And in the 2000 to '01 time frame, you
13 were the deputy administrator for HCFA?

14 A. Well, it started in -- somewhere around
15 the summer of 2000, Nancy-Ann DeParle left summer or
16 early fall, I don't remember exactly. Mike Hash
17 became the acting administrator, I became the acting
18 deputy administrator. And then about five weeks
19 before the end, Mike Hash left, and I became -- I
20 didn't change my title, but I became essentially the
21 acting top person.

22 Q. When you say five weeks before the end, is

1 have no direct knowledge of what they did.

2 Q. All right. Did you draft this language
3 that we have been reading?

4 A. I doubt that I wrote it.

5 Q. Okay. Some of the same language shows up
6 in the letter from Administrator DeParle to Congress
7 before, and I was just trying to figure out if you
8 knew who was the drafter of the language.

9 A. It's consistent with my point of view at
10 the time, but I don't remember actually being the
11 person sitting at the typewriter or at the keyboard.

12 Q. Could it have been someone in your staff?

13 A. It could well have been somebody in my
14 staff. This probably would have been produced, both
15 the letter from Miss DeParle and this letter would
16 have been produced by my executive secretariat, which
17 drafts letters. And I'm sure we had something to do
18 with it, with the letter.

19 Q. Last but not least, do you have the book
20 that has 221 in it?

21 A. This one.

22 Q. So showing you what's been marked

1 previously as 221, and ask if you've seen this
2 before?

3 A. I don't think I've seen it before. I'm
4 aware of its existence.

5 Q. This is another program memorandum to the
6 intermediaries and carriers dated November 17th of
7 2000. And it indicates that this program memorandum
8 suspends the PMAB-00-86 dated September 8th, 2000,
9 and then continues, "this is to notify you that you
10 should not use the DOJ data," the DOJ AWP's, I'm
11 paraphrasing now, in your next update of the Medicare
12 payment allowances. Do you remember why -- so let me
13 understand this, and strike all that and I'll back
14 up.

15 So is it your understanding then that the
16 carriers never did actually consider the DOJ AWP's in
17 setting Medicare reimbursement?

18 A. Well, it was to go into effect the
19 following year, so I don't believe it was ever --
20 they may have been doing some preliminary work, but I
21 don't -- I'm pretty sure it was never implemented.

22 Q. And do you know why CMS decided to pull

1 its AWP's in this memo?

2 A. I don't remember the details. I knew that
3 the Congress was getting heavily involved and was
4 preparing -- whether they had prepared or were going
5 to prepare legislation to prevent us from doing this.
6 And they were going to take this issue on themselves.
7 And in the face of that reality, I think we -- we
8 backed off. The Congress basically said, we are
9 going to deal with this issue.

10 Q. Do you know, did anyone from -- well,
11 strike that. Did you have any discussions with
12 Congress as to why they might prevent you from doing
13 this?

14 A. I can't remember that I -- I had any
15 particular -- I don't remember personally having
16 discussions. I know that we were -- there were a lot
17 of congressional letters coming in. I didn't
18 personally, that I can remember, have conversations
19 with -- with staff.

20 Q. Do you recall any reasons Congress
21 expressed as to why they might prevent you from doing
22 this?

1 A. They were hearing the same thing from
2 affected parties that were reflected in these
3 letters, both complaining about access problems and
4 alleged mistakes in how it was being implemented.
5 And Congress is always concerned when they hear about
6 access problems, so it was becoming a very big
7 political issue.

8 Q. Had you had concerns -- any concerns by
9 any pharmaceutical manufacturer with respect to
10 implementing the DOJ AWP's?

11 A. Not -- not that I can remember.

12 Q. Okay. I think that's all I've got. Can
13 we take a short break?

14 THE VIDEOGRAPHER: This is the end of tape
15 three. Off the record at 4:37.

16 (Recess.)

17 THE VIDEOGRAPHER: This is the beginning
18 of tape number four in the deposition of
19 Dr. Berenson. On the record at 2:43.

20 BY MR. MURRAY:

21 Q. Doctor, this is Brian again. You had
22 indicated right before we came back from break that

1 you had remembered the name of that center?

2 A. Yes, the center that had the
3 organizational responsibility for sending out program
4 memoranda was the Center for Beneficiary Services.

5 MS. ALBEE: Excuse me, this is Mrs. Albee.
6 Could the questioner please speak a little louder?

7 MR. MURRAY: Perfect. Sorry. We have
8 actually switched chairs here in D.C. That was my
9 last question. I'm going to pass the witness over to
10 Mr. Neil Merkl, who would like to ask you a few
11 questions. Thank you, Doctor.

12 EXAMINATION BY COUNSEL FOR DEFENDANT DEY

13 BY MR. MERKL:

14 Q. Good afternoon, Doctor. Doctor, my name
15 is Neil Merkl. I represent a company called Dey,
16 D-E-Y. Have you ever had any dealings with Dey?

17 A. No.

18 Q. And you never communicated with Dey in
19 your professional capacity at CMS/HCFA?

20 A. Not that I can remember.

21 Q. When we were talking about Exhibit 221 a
22 minute ago, that was the program memoranda that

1 rescinded the use of the DOJ AWP's. Do you have any
2 recollection at all of how you first learned that you
3 weren't going to be using those or recommending that
4 those AWP's be used any more?

5 MR. LIBMAN: Objection. Mr. Libman.
6 Asked and answered.

7 THE WITNESS: I don't remember any more
8 details about -- I certainly don't remember when I
9 first learned about it. I probably had something to
10 do with participating in a discussion to -- that
11 resulted in the issuance of that memorandum.

12 BY MR. MERKL:

13 Q. So the decision to issue the memorandum
14 was a decision made by CMS as opposed to a directive
15 received from Congress?

16 MR. DRAYCOTT: Objection.

17 THE WITNESS: I believe we did it on our
18 own with -- understanding that Congress would have so
19 directed us if we hadn't done it, but I may be wrong
20 on that.

21 BY MR. MERKL:

22 Q. Who is we?

1 A. We meaning the senior leadership at the
2 time. We are now talking about November, so I would
3 have been in that senior leadership. I don't
4 remember who else would have been involved in such
5 discussions at this time. I don't remember.

6 At that point, I was the acting deputy
7 administrator, and had moved from my position as
8 center director, and don't have a good memory as to
9 specifically what Congress's actions were, but it was
10 -- I do remember that Congress really had felt that
11 our program memorandum was -- was something they
12 wanted to suspend. And I think we anticipated that
13 and withdrew it on our own. But -- so that the
14 Congress indicated their own preference for taking up
15 the issue.

16 Q. You say the Congress felt and the Congress
17 indicated. How was it you became aware of Congress's
18 feelings and indications?

19 A. I don't remember any of the details about
20 it. I'm sure there were -- typically, I don't know
21 in this case, typically there are phone calls and
22 letters that are exchanged between, in some cases,

1 members of Congress and Senators, in other cases
2 staff, with our congressional relations people that
3 are communicated to the senior leadership of the
4 agency.

5 Q. Who are your congressional relations
6 people?

7 A. There is an Office of Legislative Affairs.
8 I don't --

9 Q. For CMS?

10 A. For CMS. Yes. As well as for the
11 department. There are two different offices.

12 Q. Do you know whose job that was at CMS?

13 A. At that time, I don't. It may have been
14 Bonnie Washington in that position at that time, but
15 she may have left by then. I don't know.

16 Q. You say you anticipated Congress might
17 direct CMS not to go ahead?

18 A. I don't remember the details. I know that
19 Congress -- no, I don't know anything. My
20 recollection, which is hazy, is that Congress was
21 preparing legislation to override the program
22 memorandum, but I may not have that exactly right.

1 Q. Did Congress have the ability to direct
2 CMS to do without passing legislation?

3 A. No.

4 MR. LIBMAN: Objection. This is
5 Mr. Libman.

6 BY MR. MERKL:

7 Q. That was a no?

8 A. I don't believe Congress can direct --
9 legislation is how Congress directs the executive
10 branch to act.

11 Q. So unless Congress actually passed
12 legislation, CMS could have gone ahead with the DOJ
13 AWP, had CMS determined to do so?

14 A. I believe that's correct.

15 Q. Okay. Now, you've already told me you
16 don't recall the individuals that participated in a
17 decision not to go ahead. Notwithstanding that you
18 don't know their names, is it possible you remember
19 who it would be by function or title or
20 responsibility?

21 A. We were in the process of -- senior
22 leadership had just changed. Nancy-Ann DeParle had

1 Dr. Berenson. On the record at 4:09.

2 BY MR. MERKL:

3 Q. Doctor, would you take a look at Exhibit
4 446 marked by Abbott's counsel earlier today, please.
5 And if you look at the bottom right-hand corner of
6 the page, in the numbers ending 2762, is a letter
7 from Congress of the United States.

8 A. Okay.

9 Q. And the first letter -- the letter I'm
10 going to talk about in Exhibit 446 is a letter dated
11 September 27th, 2000, with counsel stamp AWP 039-2762
12 through 2763, and it's on the letterhead of Edolphus
13 Towns. Do you see that letter?

14 A. Yes.

15 Q. This is a letter from the Congressional
16 Black Caucus, is that correct?

17 A. I presume, but looking at some of the
18 names -- do they say they are from -- yes. I don't
19 know -- I assume that's right, but I don't really --

20 Q. To Secretary Shalala?

21 A. Yes.

22 Q. Dated September 27, 2000, correct?

1 A. Correct.

2 Q. And it addresses the proposed new AWP
3 that the DOJ was suggesting you use as a basis for
4 reimbursement, correct?

5 A. Correct.

6 Q. Do you recall seeing this letter?

7 A. No.

8 Q. In or about 2000?

9 A. I don't recall seeing it.

10 Q. Earlier you told me when HCFA decided not
11 to go ahead and use the DOJ AWP that it was in
12 response in part to concerns expressed by Congress.
13 Do you recall that?

14 A. That's correct. I did say that.

15 Q. Does this letter reflect the concerns you
16 were telling me about before or is this something
17 else?

18 A. This would be exactly the kind of concerns
19 that Congress would express.

20 Q. Now, when you say you don't recall this
21 letter, do you have any reason to believe one way or
22 the other whether you saw it or did not see it at the

1 time. Is this the type of thing you would have seen?

2 A. No. It went to Donna Shalala, who was not
3 CMS. So if it had gone to our administrator, I
4 probably would have seen it. It might have been
5 routed to somebody at CMS, but this would not be
6 something I would more likely see, because it goes to
7 the department. I mean, it wouldn't be something I
8 would routinely see, because it would be -- that
9 response to it would be handled at the department and
10 it would be less likely that I would be involved in
11 it, although I might have been. I just don't
12 remember.

13 Q. But does this letter accurately reflect
14 concerns that you became -- that you were made aware
15 of that Congress was expressing about the change?

16 MR. DRAYCOTT: Objection.

17 THE WITNESS: This is the kind of concern
18 when I said earlier that politics became a factor,
19 this is the kind of thing I'm referring to. Yes.

20 BY MR. MERKL:

21 Q. Well --

22 A. And I'm not saying politics in a

1 pejorative sense.

2 Q. For instance, if we look at the second
3 paragraph of the letter from Congressman Towns, he
4 says, "this pricing change directed by HCFA will
5 result in a 66 percentage in the respiratory
6 medication Albuterol. This reduction will
7 effectively force the current Medicare providers of
8 home respiratory medication out of business and
9 eliminate this benefit to the African-American
10 community." Is he correct?

11 MR. DRAYCOTT: Objection.

12 MS. ALBEE: Objection.

13 THE WITNESS: I have no idea if he is
14 correct. Just the fact that it's here doesn't make
15 it correct, but it's -- I don't know.

16 BY MR. MERKL:

17 Q. But you have no reason and you had no
18 evidence at the time to suggest he wasn't telling the
19 truth here, right?

20 MR. DRAYCOTT: Objection.

21 THE WITNESS: A lot of this -- I have no
22 reason to think that he is wrong about the 66 percent

1 reduction, that's verifiable, a projection about
2 people going out of business and eliminating care for
3 the African-American community, I don't have any
4 prior assumption whether this is correct or not
5 correct.

6 BY MR. MERKL:

7 Q. Well, isn't it fair to say that this was a
8 concern as expressed by Congress that you would have
9 to take seriously?

10 A. Absolutely.

11 MR. DRAYCOTT: Objection.

12 BY MR. MERKL:

13 Q. And you did take it seriously?

14 A. We did take it seriously.

15 Q. Would you take a look at the next letter,
16 please, starting at page AWP 039-2765. Again, to
17 Secretary Shalala from members of Congress. The
18 first one is Pete Sessions.

19 A. Yes.

20 Q. Do you recognize this letter?

21 A. No.

22 Q. Would you just take a look through it and

1 tell me is this the type of concern that was in fact
2 expressed to you in or about 2000 about the potential
3 use of DOJ AWP's?

4 A. This is the type of concern that was being
5 expressed. Yes.

6 Q. And the substance of what's in here in
7 fact was expressed to you, correct?

8 A. For cancer drugs, yes.

9 Q. And again, you took these concerns
10 seriously, right?

11 MR. DRAYCOTT: Objection.

12 THE WITNESS: Any letter from Congress,
13 you take seriously.

14 BY MR. MERKL:

15 Q. And this letter here, this July 20th
16 letter and the letter that we just looked at from the
17 black -- Congressional Black Caucus were in fact two
18 of the reasons that you elected to continue using the
19 AWP's as published in the Red Book and Blue Book for
20 reimbursement of Medicare rather than going with the
21 DOJ numbers, correct?

22 MR. DRAYCOTT: Objection.

1 THE WITNESS: Yes. That's correct.

2 BY MR. MERKL:

3 Q. Would you take a look at the next letter,
4 please. This is a letter from the Senate dated
5 August 1st, 2000. To Secretary Shalala from John
6 Breaux, Orrin Hatch, Bill Frist, Mary Landrieu and
7 Max Baucus. Take a look. Do you recall this letter?

8 A. No.

9 Q. You don't recall seeing it?

10 A. No.

11 Q. Would you take a look, and tell me if you
12 recall being aware of the sum and substance of the
13 concerns being expressed in this letter?

14 A. I actually hadn't heard a couple of these
15 concerns.

16 Q. Which ones are they?

17 A. The impact on First DataBank's current
18 contract with subscribers, the effect on private
19 insurance contracts. The impact of reloading data on
20 to computers for HCFA. And again, private insurance
21 companies. So those concerns, I wasn't generally
22 aware of.